Center for Devices and Radiological Health

Health Hazard Evaluation ☒ **Health Risk Assessment ☐**

RES #: 59317 **ORACLE #:** _____ **RECALL # (s):** _____

Date: August 19, 2011 **Safety Officer:** LT John Diehl

I. Product Data

Panel Code:	**Device Name:** SynchroMed II Implantable Infusion Pump
Product Code: LKK	
Model:	**Lot/Serial Numbers:** Model 8637-20 and 8637-40

Marketing Status (Include 510(K) or PMA Number, Specify if Exempt From 510(K) :
P860004/S056

Total Number of Devices in Distribution: 139,653

U.S.: 105,002	**Foreign:** 34,651

Number of Devices Subject to Review:

U.S.: 105,002	**Foreign:** 34,651

Manufacturer Address:
MDT Puerto Rico Operations Co., Juncos
Road #31, km.24, hm 4
Ceiba Norte Industrial Park,
Juncos, Puerto Rico 00777

Parent Company
Medtronic, Inc – Neuromodulation
7000 Central Ave NE
Minneapolis, Minnesota 55432-3568
T: 763-526-9738
F: 651-367-0814
FEI: 2182207

Product Description (Include Intended Use from labeling or known off-label uses):
The SynchroMed Implantable Infusion System is an implantable programmable infusion pump used to deliver morphine sulfate, ziconotide and Lioresal for the treatment of chronic pain, severe chronic pain and severe spasticity, respectively. The SynchroMed Implantable Infusion System is also indicated for delivery of floxuridine and methotrexate for the treatment of primary or metastatic cancer. By use of a sterile syringe and needle, the drug is injected into the pump reservoir through the refill septum. The physician uses an external programmer to program the infusion rate (i.e., prescription). The propellant within the pump provides pressure which pushes on the drug reservoir, causing the drug to flow through the internal bacterial filter into the internal pump tubing. A three-pronged pump head roller assembly rotates at a speed commensurate with the physician-programmed dose, which controls the drug infusion rate exiting the pump via the catheter connector.

The SynchroMed II Pump is supplied in 20 ml and 40 ml reservoir sizes. In the United States, the SynchroMed II Pump is indicated when patient therapy requires chronic infusion of specific drugs.

II. Problem Definition and Analysis

Reason for Recall or Risk Assessment

- **Description of the Defect, Malfunction or Error in Use of the Device:**
  According to the FDA Investigator (Investigator), battery resistivity can lead to low battery reset and pre-mature early replacement indicator (ERI). Low battery re-set can lead to pump failing to infuse. Drugs such as Baclofen cannot be abruptly stopped due to risk of death.

  According to the firm, pumps were returned from the field after exhibiting low battery reset and premature ERI. The SynchroMed II battery part number (b)(4) specification states the (b)(4) (b)(4) Real time testing of (b)(4) batteries by the Medtronic battery supplier revealed that the resistance was exceeding (b)(4) ohms in (b)(4) batteries. According to Medtronic report (b)(4), " (b)(4) (b)(4)

- **Root Cause of the Problem (If Known)**
  According to the investigator, resistive film develops between cathode pellet and cathode current collector. The physical cause of the film is not yet known by the firm.

  According to the firm, (b)(4) (b)(4) has been identified as the source of battery drop voltage during high current demands. A (b)(4) film forms on the cathode surface. Of all battery cells studied, this resistance film was seen. The (b)(4) film may cause variations in the battery voltage that can prematurely activate the pump ERI, end of service, and/or cause a low battery reset.

- **Factors that May Contribute to Product Risk (i.e. Device Design, Manufacturing Problems or User Error):**
  According to the investigator, design of battery and manufacturing variability in battery manufacturing

  According to the firm, the root cause pertaining to why the resistive film forms in battery cells is unknown.

- **If Device Failure Occurs is it Easily Recognized by User?**
  Users may not recognize a device failure until the device has failed and they begin to experience clinical symptoms consistent with termination of therapy. However, sudden cessation of intrathecal baclofen may result in serious injury and death. Oral Baclofen may be effective in preventing serious injuries or death. A Functional alarm may alert users to device failure prior symptoms occur, however it is unknown at this time whether this failure may cause the alarm to fail.

  According to the firm, the reduced battery performance issue could manifest itself clinically as a return of underlying symptoms, withdrawal symptoms, and the potential for complications due to withdrawal.

Manufacturer's CAPA Investigation (If Available):

- **Summary:** According to the firm, as of May 2009, they had identified nine SynchroMed II drug pumps that were returned from the field after exhibiting low battery reset and premature Elective Replacement Indicator (ERI). These devices were analyzed and found to be experiencing reduced battery performance, which occurred after (b)(4) months of implant duration. The anticipated battery life for SynchroMed II pumps is seven years (84 months). Engineering analysis indicated that the reduced battery performance was due to (b)(4) over time. The (b)(4) may cause variations in battery voltage that can prematurely activate the pumps ERI, End of Service (EOS), and/or cause a Low Battery Reset. This reduced battery performance issue could manifest itself clinically as a return of underlying symptoms, withdrawal symptoms, and the potential for complications due to withdrawal. Testing of batteries from field returns, as well as production lifetest samples indicates that some batteries of this design can experience elevated resistance that can result in premature ERI or unacceptably low supply voltage during high current demands.

- **Date of Analysis:** HHA initiated by firm on November 10, 2008, and completed on June 16, 2009. CAPA 1550 opened by firm on September 12, 2008

- *Update to May 2011 HRA* According to the firm, as of May 31, 2011, they have confirmed that 55 SynchroMed II drug pumps were returned from the field worldwide after exhibiting low battery reset and/or premature ERI. These devices were analyzed by the firm and found to be experiencing reduced battery performance, which occurred between (b)(4) months implant duration. As stated previously, the anticipated battery life for SynchroMed II pumps is 84 months. All but one of the (b)(4) reports occurred in pumps that were included in the affected population for the 2009 recall (i.e. they were built with batteries manufactured prior to March 17, 2005).

- **Firm's Estimate of Number of Devices that will develop the Defect and/or Fail:** According to firm, based on survival analysis of the implant duration of the suspect population, the estimated proportion of devices that may fail by five years post implant is (b)(4) Based on reliability modeling of the affected batteries, Medtronic estimates that up to (b)(4) of the suspect population may be at risk for this battery mode failure.

    - **How Many Devices from the Affected Lots Are Expected to Have or Develop the Defect?** Between August 15, 2003, and March 16, 2005, the worldwide population of active implanted pumps with batteries subject to resistivity issues was (b)(4). All of these lots could develop the defect.

    - **How Many Devices with the Defect are Likely to Exhibit the Failure over the Lifetime of the Device?** The firm estimated that only (b)(4) of these 14,852 pumps were likely to exhibit this failure.

    - **Of Those Devices that Fail, How many are Likely to Cause Injury if Used?** Of the (b)(4) pumps the firm estimated to fail:
        - (b)(4)
        - (b)(4)

Update to May 2011 HRA
Pumps with batteries manufactured prior to March 17, 2005: As of May 31, 2011, statistical analysis of the confirmed cases has estimated the cumulative probability for pump failure due to this issue to be (b)(4) at 84 months post implant with an upper bound estimate of (b)(4) Note that this (b)(4) cumulative probability applies to a patient newly implanted, and reflects the risk over the full 7 years of expected pump life. The majority of pumps currently

implanted were manufactured 6 years ago and therefore the probability for pump failure between now and end of service life is less than (b)(4) These rates are within the overall rates estimated in the July 2009 communication.

Pumps with batteries manufactured on or after March 17, 2005: As of May 31, 2011, statistical analysis of the confirmed case has estimated the cumulative probability for pump failure due to this issue to be (b)(4), at 72 months post implant with an upper bound estimate of (b)(4)

- **Firm's Conclusion about Health Risk (Attach a Copy of Firm's HHEs or HHAs):**

According to the firm, (b)(4) (b)(4) (b)(4) More details are included in the firm's HHA.

In July 2009, the firm issued an Urgent Medical Device Correction to make health professionals aware of the battery performance issues with the SynchroMed II pumps. Also, in CAPA 1550, the firm concluded that the elevated resistance values (> (b)(4) were not a predictor of pump performance. The firm wrote a deviation ((b)(4)) to allow batteries to exceed (b)(4) specification. The firm was not able to discover the underlying cause of the high resistance in batteries and the physical cause of the resistive film that develops within the battery is still not known.

Update to May 2011 HRA
Beginning July 5, 2011, the firm began mailing physicians (based on registration data for the SynchroMed II pump) a letter that contained updated information regarding the scope and occurrence of this battery performance issue, and that emphasized previously communicated patient management recommendations. The firm made it clear in their communication that Patients receiving intrathecal baclofen therapy are at risk for baclofen withdrawal syndrome, which can lead to a life threatening condition if not promptly and effectively treated. This issue is being treated as a Class 1 recall by the firm.

- **Any FDA Comments:**

FDA has concerns with the firms risk assessment, including estimates of failure rate. For example, the firm estimated that (b)(4) of affected pumps will exhibit this failure, however ~ (b)(4) of the batteries tested failed. The firm has not provided CDRH with data to determine whether resistivity issues will develop in battery production lots manufactured after December 2006 because it takes time for the resistive film to develop between the cathode pellet and the cathode current collector. The firm continues to manufacture and distribute pumps with these defective batteries.

The FDA is concerned that if the pump resets to a default value that the pump may not notify the user that this is occurring. Also, the FDA has concerns with the firms statement that these pump failures will begin to occur after (b)(4) months of use as they have not provided data supporting this claim. The firm should provide data to support their claim that the pump may fail between (b)(4) months and not sooner.

The firm has submitted a PMA supplement to CDRH for the re-design of the SynchroMed II battery, but, as of the investigators April 3, 2011 request, this supplement has not been approved. Currently, FDA is reviewing the firm's re-designed battery submission and there are concerns that the pump alarm may not work properly when or if the battery fails. If the pump were to have a short circuit (either an battery internal short or an external component that causes the battery terminals to short-circuit) that does not recover, there would be no voltage available to sound an alarm or, if the alarm system fails as a result of a component failure, the pump system continues to operate normally, however the alarm system is no longer notifies the patient (or care giver) if the battery fails and pump resets. This does not satisfy the requirements of the single fault safe condition required by EN 45502-1:1998 clause 19.3. Does the pump have a backup alarm system? If the pump's alarm circuit is not functioning, how will the patient/caregiver be notified? FDA will continue to review the firm's supplement for the re-design of the SynchroMed II battery.

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Update to May 2011 HRA
The firm's PMA supplement for the re-design of the SynchroMed II battery was approved by FDA on July 1, 2011.

Adverse Events, Complaints and Problems or Incidents that may be related to the Device Defect:

Number of Complaints 507 **Malfunction Reports** *

Injuries Reported **U.S.** * **International** _____

Deaths Reported **U.S.** *9 **International** _____

*It can not be definitively determined how many deaths were attributed to the battery resistivity issue. Please refer to the PAER analysis provided by OSB as two separate MAUDE searches were conducted.

Sources:

Manufacturer _____ **Inspection** 52 **MDR's** *

Explanation:
According to the investigator, Medtronic Puerto Rico Operations Company in Juncos, Puerto Rico assembles the finished SynchroMed II Infusion Pump device. All information regarding returned device analysis, MDR filing, etc is maintained at Medtronic Neuromodulation, 7000 Central Ave NE, mailstop RCC150, Minneapolis, Minnesota 55432.

Per the OSB PAER: The first search of the MAUDE database was conducted using the following criteria: the date entered between August 1, 2009, and April 26, 2011; product codes LKK and manufacturer short name. This search generated a total of 6,754 MDRs. Then, a text search was conducted using the term "battery". This resulted in 381 MDRs. Types of events were reported as: 8 deaths, 230 injuries, and 143 malfunctions. Of these, 61 reports or 8.57% utilized a device problem code of "low battery" and an additional 31 reports or 4.22% utilized a device problem code of "battery issue".

A second search of the MAUDE database was conducted using the recall number Z-2276-2009. This resulted in 74 MDRs. Types of events were reported as: 1 death, 43 injuries, and 30 malfunctions. Of these, 9 reports or 7.38% utilized a device problem code of "low battery," and an additional 13 reports or 10.66% utilized a device problem code of "battery issue." Please note that multiple device codes may be reported in each MDR, and therefore the total number of problem codes may exceed the number of MDRs.

The FDA is concerned that the MDR reports attributed to this issue may be underreported because the firm has a history of reporting SynchroMed-related adverse events to CDER instead of CDRH.

Describe the Complaints and Injuries Reported to Date:
According to the investigator, per CDRH and OSB request, the inspectional team was asked to review MDR 3007566237-2010-07017 regarding a patient death (Baclofen patient) whose pump was found to have a high battery resistivity and was in a low-battery reset mode.

Per the CDRH/OSB PAER completed:

RE: Patient Death Reports

General Information	Event Description and Additional Notes
MDR 3007566237-2010-04748 SYNCHROMED II Model: 8637	It was reported that the pt underwent elective pump replacement; the pump was replaced due to a "low battery condition (alarm was generated)". Following the replacement, the pt was admitted to the intensive care unit for 10 days and died of a suspected sudden cardiac arrest. It was noted that "pump diagnostics post-operatively had all been satisfactory". At autopsy, it was noted that "the catheter was divided cleanly in two in the pump pocket". The presumption was that this was perioperative though this hadn't been definitely established. The investigation was ongoing. It was unk if the devices contributed to the pt's death. The device system was used to deliver Baclofen. Add'l info has been requested. A follow-up report will be sent if add'l info becomes available.

General Information	Event Description and Additional Notes
MDR 3007566237-2010-07017 SYNCHROMED II, Model: 863740 Serial Number: NGV003562N	The pump was refilled Thursday 8/19/2010 with Baclofen 2,000mcg/ml and set at a dose of 12.5mcg/day. Late the following Saturday the patient awoke screaming in pain and his mother gave him 20mg oral Baclofen and soma. He awoke in pain again at 5:30am Sunday and was given an additional 20mg of oral Baclofen; the paramedics were called. They arrived at 8:00am Sunday and transported the patient to the emergency department. The patient arrived unresponsive and with a temperature of 109. He was pronounced dead at 9:30am that day. The medical examiner believed Baclofen withdrawal was a possible cause of death. Telemetry strips correlating to pump examination on 8/27/2010 indicated that the pump had reset and was in safe state. Analysis results were pending. Supplement report indicated: Final device analysis of the pump revealed battery resistance high. Final device analysis of the returned catheter segments revealed no significant anomalies; acceptable catheter testing. An additional information request was generated to the firm. Please see PAER for details.

Update to May 2011 HRA

According to the firm, there are 55 reports associated with primary finding or low battery reset or premature ERI as confirmed by Medtronic:

Any of the following terms or conditions reported:	**Qualitative Severity**	**Total Reports**
Death	Death	1
Intensive care treatment, extended hospitalization, exaggerated rebound spasticity, altered mental state	Life Threatening	8
Return of Underlying symptoms, medical intervention, surgical revision ore observation and none of terms for severity 4	Serious Injury	46
Adverse events reported, but no medical intervention	Non-Serious Injury	0
Report of battery issue, but no adverse symptoms reported	No Injury	0
	Total	**55**

A listing of the MDR report numbers that have been reported is included in Medtronic's HHA (ref: NDHF1119-102866). Two MDR numbers were not available at the time the HHA was written, these are listed below:

PCR 553508: 3007566237201104752
PCR 555341: 3007566237201104517

III. Health Risks
TO BE COMPLETED BY MEDICAL OFFICER OR COMMITTEE

THE FOLLOWING ASSESSMENT IS BASED ON CURRENTLY AVAILABLE INFORMATION. CONCLUSIONS MAY CHANGE IF ADDITIONAL INFORMATION BECOMES AVAILABLE IN THE FUTURE.

Immediate and Long Range Health Consequences:

A. **Describe the Immediate and Long Range Health Consequences (Injuries or Illnesses) That May Result from Use of or Exposure to the Defective Device. (Include Known Off Label Uses)** Use of a defective device may result in underdosing or abrupt cessation of therapy. The health consequences due to underdosing or abrupt cessation of therapy may include rebound pain, return of spasticity and delay of therapy. Abrupt withdrawal of Baclofen can lead to rebound spasticity, seizures, fever, multi-organ system failure and death. When this failure occurs, patients will require additional surgery and anesthesia to replace the device, exposing patients to the risks associated with surgery and anesthesia, and may include serious injuries or death.

B. **Describe Any Factors That May Mitigate the Risk:** Immediate recognition of withdrawal symptoms and/or device alarm by the user may mitigate the risk associated with use of this defective product.

C. **What Segment of the Population is Most at Risk? (E.g. Infants, Elderly, Pregnant Women, Critically Ill Patients, Immunocompromised, etc.)** Elderly, Critically ill, Patients on Baclofen

D. **Does the Health Consequence Have Significant Public Health Impact Beyond Users (e.g. Spread of Serious Infection to Others)?** No

Assess the Hazards Associated with Use of the Defective Product – When failure of the battery occurs, it will require surgery to replace the battery.

Check All that Might Occur:

Population at Greatest Risk	Overall Population Using Device	
☒	☒	Life-threatening (death has or could occur)
☒	☒	Results in permanent impairment of body function or permanent damage to a body structure.
☒	☒	Necessitates medical or surgical intervention.
☐	☐	Temporary or reversible (without medical intervention).
☐	☐	Limited (transient, minor impairment or complaints).
☐	☐	No adverse health consequences.

Explanation:

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IV. PROBABILITY

TO BE COMPLETED BY MEDICAL OFFICER OR COMMITTEE

Assess the Probability that Use of, or Exposure to, Product under Recall will Cause

A. Serious Adverse Health Consequences or Death

	Overall Population Using Device	Population at Greatest Risk
Reasonable Probability	☐	☒
Remote Probability	☒	☐
Not Likely	☐	☐
Explanation / Comments:		

B. Temporary or Medically Reversible Adverse Health Consequences

	Overall Population Using Device	Population at Greatest Risk
May Cause	☒	☒
Not Likely to Cause	☐	☐
Explanation / Comments:		

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Signatures	Date	Printed Name, Title and Office
Steven Osborne MD	8/19/11	Steven Osborne Medical Officer Office of Compliance
LT JOHN DIEHL	8/19/11	JOHN DIEHL, CDRH/OC/DEA/CO

U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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New Search

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Class 1 Recall
Medtronic SynchroMed II

See Related Information[20]

Date Posted	August 29, 2011
Recall Number	Z-3043-2011
Product	Medtronic SynchroMed II, Model 8637, (The SynchroMed® II Pump is supplied in 20 ml or 40 ml reservoir size.) Sterilized using ethylene oxide. The pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implantable components of the SynchroMed II Infusion System include the pump, catheter, and catheter accessories.
Code Information	serial numbers: NGP000370R thru NGP002152R, NGP000565N thru NGP034132N, NGP005103H thru NGP350081H, NGP350083H, NGP350086H thru NGP350092H, , NGP350094H thru NGP350414H, NGP350416H, NGP350417H, NGP350418H, NGP350419H, NGP350421H, NGP350422H, NGP350423H, NGP350424H, NGP350425H, NGP350427H, NGP350428H, NGP350429H, NGP350431H thru NGP350464H, NGP350466H, NGP350468H thru NGP350506H, NGP350509H thru NGP350576H, NGP350578H, NGP350579H, NGP350580H, NGP350581H, NGP350582H, NGP350583H, NGP350585H thru NGP350599H, NGP350601H, NGP350602H, NGP350603H, NGP350604H, NGP350606H thru NGP350814H, NGP350816H thru NGP350837H, NGP350839H thru NGP350852H, NGP350860H thru NGP350880H, NGP350882H thru NGP350905H, NGP350907H thru NGP350916H, NGP350918H thru NGP351197H, NGP351199H thru NGP351229H, NGP351231H thru NGP351258H, NGP351260H thru NGP351302H, NGP351304H thru NGP351337H, NGP351339H thru NGP351396H, NGP351398H thru NGP351456H, NGP351458H, NGP351459H, NGP351460H, NGP351461H, NGP351463H, NGP351464H, NGP351465H, NGP351467H thru NGP351497H, NGP351499H thru NGP351601H, NGP351603H thru NGP351617H, NGP351619H thru NGP351651H, NGP351653H, NGP351654H, NGP351656H thru NGP351800H, NGP351802H thru NGP351809H, NGP351811H thru NGP351824H, NGP351826H thru NGP351863H, NGP351865H, NGP351866H, NGP351868H thru NGP351904H, NGP351906H thru NGP351919H, NGP351921H thru NGP351996H, NGP351998H, NGP351999H, NGP352000H, NGP352001H, NGP352002H, NGP352003H, NGP352004H, NGP352005H, NGP352007H, NGP352009H thru NGP352149H, NGP352151H thru NGP352221H, NGP352223H thru NGP352250H, NGP352252H thru NGP352279H, NGP352281H thru NGP352403H, NGP352405H thru NGP352417H, NGP352419H thru NGP352442H, NGP352444H thru NGP352473H, NGP352475H, NGP352476H, NGP352477H, NGP352478H, NGP352480H thru NGP352548H, NGP352550H thru NGP352558H, NGP352560H, NGP352561H, NGP352562H, NGP352564H thru NGP352756H, NGP352758H thru NGP352778H, NGP352780H thru NGP352896H, NGP352898H thru NGP352918H, NGP352920H thru NGP353016H, NGP353018H thru NGP353085H, NGP353087H thru NGP353252H, NGP353254H thru NGP353296H, NGP353298H, NGP353299H, NGP353300H, NGP353301H, NGP353302H, NGP353303H, NGP353304H, NGP353305H, NGP353306H, NGP353308H thru NGP353364H, NGP353366H, NGP353367H, NGP353368H, NGP353369H, NGP353371H thru NGP353477H, NGP353479H, NGP353480H, NGP353481H, NGP353482H, NGP353484H thru NGP353505H, NGP353507H thru NGP353531H, NGP353533H thru NGP353599H, NGP353601H thru NGP353637H, NGP353639H, NGP353640H, NGP353641H, NGP353642H, NGP353643H, NGP353644H, NGP353645H, NGP353646H, NGP353647H, NGP353648H, NGP353649H, NGP353651H thru NGP353664H, NGP353666H thru NGP353739H, NGP353741H thru NGP353750H, NGP353752H, NGP353753H, NGP353754H, NGP353755H, NGP353756H, NGP353757H, NGP353758H, NGP353759H, NGP353760H, NGP353761H, NGP353763H thru NGP353789H, NGP353791H thru NGP353821H, NGP353823H, NGP353824H, NGP353825H, NGP353826H, NGP353827H, NGP353828H, NGP353830H, NGP353832H thru NGP353923H, thru NGP353947H, NGP353949H, NGP353951H, NGP353952H, NGP353953H, NGP353954H, NGP353956H, NGP353957H, NGP353958H, NGP353959H, NGP353960H, NGP353961H, NGP353962H, NGP353964H, NGP353965H, NGP353966H, NGP353967H, NGP353968H, NGP353969H, NGP353970H, NGP353971H, NGP353972H, NGP353973H, NGP353974H, NGP353976H, NGP353977H, NGP353978H, NGP353979H, NGP353980H, NGP353981H, NGP353982H, NGP353984H, NGP353985H, NGP353986H, NGP353987H, NGP353988H, NGP353989H, NGP353990H, NGP353991H, NGP353992H, NGP353993H, NGP353994H, NGP353995H, NGP353996H, NGP353999H, NGP354000H, NGP354001H, NGP354003H, NGP354004H, NGP354005H, NGP354006H,

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Recalling Firm/ Manufacturer
Medtronic, Inc. - Neuromodulation
7000 Central Ave NE
Minneapolis, Minnesota 55432-3568

Consumer Instructions
Contact the recalling firm for information

For Additional Information Contact
Medtronic Patient Services
800-510-6735

Reason for Recall
Medtronic is updating information regarding the potential for reduced battery performance that can lead to sudden loss of therapy in a small percentage of Medtronic Model 8647 SynchroMed II pumps that was communicated with Healthcare providers in July 2009. The purpose of the current communication is to provide updated information regarding the scope and occurrence of this issue and to emphasize

Action
Medtronic Neuromodulation notified physicians with an Urgent Medical Device Correction letter beginning July 05, 2011. A press was issued July 08, 2011. The letter described the issue, severity, recommendations if they notice issue, and patient management recommendations. UPDATE: in November 2011, MDT began to exchange unused pumps in inventory with pumps that contained the new battery. A letter dated November 2011 was left behind at locations in which the MDT representative swapped out the devices.

Quantity in Commerce
139,653 (105,002 US, 34,61 OUS)

Distribution
Worldwide including USA, Puerto Rico, Algeria, Aruba, Australia, Austria, Belarus, Belgium, Brazil, Chile. Colombia. Costa Rica. Croatia, Cyprus, Czech Republic, Denmark, Dominican Republic, Egypt, Finland, France, Germany, Greece, Hungary, Iceland, India, Iran Iraq, Ireland, Israel Italy, Jordan, Kuwait, Lebanon, Lithuania, Luxembourg, Malta, Martinique, Mexico, Morocco, Netherlands, Netherlands Antilles, New Caledonia, New Zealand, Norway, Panama, Poland, Portugal, Qatar, Reunion, Romania, Russian Federation, San Marino, Saudi Arabia, Serbia, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Tunisia, Turkey, United Arab Emirates, United Kingdom, and Uruguay.